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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,806	05/04/2001	Jen Sheen	00786/389002	7904
21559	7590	10/19/2006	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER

1638

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/848,806	Applicant(s) SHEEN, JEN	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 17-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-16 and 54-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's submission filed on August 9, 2006 has been entered.

Claims 1-57 are pending.

Claims 1, 54 and 56 currently amended.

Claims 9 and 17-53 are withdrawn.

Claims 1-8, 10-16 and 54-57 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10-16 and 54-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The method as currently claimed requires introducing a transgene that overexpresses a nucleic acid molecule encoding a calcium dependent protein kinase (CDPK) polypeptide into a plant cell that is susceptible to a disease-causing pathogen and regenerating a plant from said plant cell. Introducing a transgene that

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overexpresses a nucleic acid molecule encoding a calcium dependent protein kinase (CDPK) polypeptide into a plant cell that is susceptible to a disease-causing pathogen and regenerating a plant from said plant cell does not find support in the specification as filed, and thus constitutes new matter.

Claim Rejections - 35 USC § 102

Claims 1-8, 10-16 and 54-57 remain rejected under 35 U.S.C. 102(b) as being anticipated by Sheen (WO 98/26045, published 18 June 1998), for the reasons of record.

Applicant's arguments filed August 9, 2006 have been fully considered but they are not persuasive.

Applicant maintains that the rejection should be withdrawn because the cited reference fails to teach or suggest this step of introducing the nucleic acid molecule into a plant cell that is "susceptible to a disease-causing pathogen", and accordingly, does not anticipate claim 1.

Applicant also maintains that, to anticipate claim 1, WO 98/26045 each must disclose every limitation of the claimed method, either explicitly or inherently, and asserts that it is not inherent in the disclosure of WO 98/26045 that the plant cells used for the transformation experiments were either susceptible to a disease causing pathogen or would become resistant to a disease-causing pathogen upon introduction of the nucleic acids falling within the scope of claim 1.

Applicant points out that the cited reference is silent on these issues, and there is no evidence indicating that plant cells susceptible to disease-causing pathogens are necessarily present.

Applicant also points out that the mere possibility that WO 98/26045 might be understood by one of skill in the art to disclose plant cell susceptible to a disease-causing organism is

insufficient to show that it is inherently disclosed in the reference. WO 98/26045 does not satisfy the standard for inherency. (reply page 13)

With respect to Applicant's argument that it is not inherent in the disclosure of WO 98/26045 that the plant cells used for the transformation experiments were susceptible to a disease causing pathogen, the Examiner maintains that it is inherent, as it was known in the art at the time of filing that plant cells are inherently susceptible to plant pathogens, including the cells of plant species disclosed by Sheen, i.e. cruciferous plants, maize and tomato.

See, for example, Agrios G.N. (Plant Pathology, Fourth Edition, 635 pp. New York, USA: Academic Press, 1997), who defines disease in plants as a series of invisible and visible responses of plant cells and tissues to a pathogenic microorganism that result in changes in the form, function or integrity of the plant (page 4). Agrios G.N. also teaches that tens of thousands of diseases affect cultivated plants, and that on the average, each kind of crop plant can be affected by a hundred or more plant diseases (pages 4-5). Agrios G.N. additionally teaches examples of diseases affecting the plant species disclosed by Sheen, cruciferous plants, maize and tomato (page 29 Table 1-1; page 30 Table 1-2; page 249 lines 29-30 and 33; pages 433-434 and Figure 12-26; page 519 column 1 first paragraph).

Further, the method as disclosed does not require that nucleic acids falling within the scope of claim 1 be introduced into a plant cell that is susceptible to a disease-causing pathogen; the method as disclosed requires only that nucleic acids falling within the scope of claim 1 be introduced into a plant cell (page 2 lines 1-18; page 6 lines 21-25; pages 22-24; pages 26-28).

With respect to Applicant's argument that it is not inherent in the disclosure of WO 98/26045 that the plant cells used for the transformation experiments would become resistant to a

disease-causing pathogen upon introduction of the nucleic acids falling within the scope of claim 1, the Examiner maintains that it is inherent, as the specific effect claimed is presumed to be mediated by an inherent function of the CDPK polypeptide expressed in the plant cell, since all that is technically required to practice the claimed invention is the transformation of a plant with a nucleic acid molecule encoding a calcium dependent protein kinase (CDPK) polypeptide of SEQ ID NO:1 or having 95% identity to SEQ ID NO:1, with the subsequent expression of the polypeptide occurring as a consequence of said transformation step. Further, the specific effect claimed is disclosed as being mediated by expression of the CDPK polypeptide (for example at page 2 lines 1-7; page 3 lines 10-12 and 22-24; page 4 lines 10-13 and 22-26; page 10 lines 10-12). In this regard it is noted that the claimed method is technically indistinguishable from the method taught by Sheen, as both the claimed method and the method taught by Sheen require only transforming a plant with a nucleic acid molecule encoding a calcium dependent protein kinase (CDPK) polypeptide of SEQ ID NO:1 or having 95% identity to SEQ ID NO:1, with the subsequent expression of the polypeptide occurring as a consequence of said transformation step.

See *Integra Life Sciences I Ltd. v. Merck KGaA*, 50 USPQ2d 1846 (DC SCalf, 1999) which teaches that a reference teaching a process may anticipate claims drawn to a method comprising the same process steps, despite the recitation of a different intended use in the preamble or the later discovery of a particular property of one of the starting materials or end products. See also *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993), which teaches that a reference teaching a claimed process, wherein one of the claimed properties of a product used in the prior art process is inherent but undisclosed by the reference, may be properly applied as art against the claimed process.

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The rejected claims recite no technical features that distinguish Applicant's claimed method from the method taught by Sheen, and the claimed method relies on the use of compositions (calcium dependent protein kinase and plant cell that is susceptible to a disease-causing pathogen) that are distinguished from the prior art compositions on the basis of inherent functional characteristics. Accordingly, the claimed invention is anticipated by the prior art reference.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia Collins
Primary Examiner
Art Unit 1638

CC


10/16/06